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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOSPIRA, INC. and ORION CORPORATION, Plaintiffs and Counterclaim Defendants, v. SANDOZ INTERNATIONAL GmbH, SANDOZ INC., and SANDOZ CANADA Defendants and Counterclaim Plaintiffs.	CIVIL ACTION NO. 3:09-cv-04591 (MLC/TJB) **REDACTED VERSION**

MEMORANDUM IN SUPPORT OF SANDOZ INC.'S AND SANDOZ CANADA INC.'S MOTION FOR LEAVE TO FILE FIRST AMENDED ANSWERS, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

TABLE OF AUTHORITIES
(continued)

Page(s)

Defendants and Counterclaim Plaintiffs Sandoz Inc. and Sandoz Canada Inc. ("Sandoz Canada," collectively with Sandoz Inc., "Sandoz") respectfully submit this memorandum in support of their motion pursuant to Federal Rule of Civil Procedure 15(a) for leave to file their First Amended Answers, Affirmative Defenses, and Counterclaims amending their already well-pleaded inequitable conduct defenses and counterclaims. (Mooney Exs. A-D.)[1] For the reasons set forth below, Sandoz Inc. and Sandoz Canada should be granted leave to amend their counterclaims in view of information learned during discovery and in recent depositions.

BACKGROUND

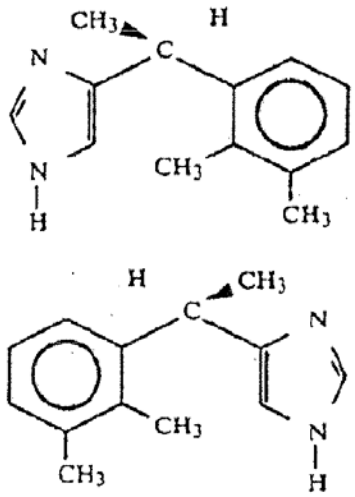
A. The Parties and the Patents

On September 4, 2009, Plaintiffs Hospira Inc. and Orion Corporation (collectively, "Plaintiffs") commenced this action against Sandoz Inc. for alleged infringement of U.S. Patent Nos. 4,910,214 (the "'214 Patent") and 6,716,867 (the "'867 Patent"; collectively with the '214 Patent, the "Patents-In-Suit") under 35 U.S.C. § 271(e), based on the filing of Abbreviated New Drug Application No. 91-465. (D.E. 1, Complaint.) Plaintiffs added Sandoz Canada to the case by Amended Complaint on May 17, 2010. (D.E. 55.)

The Patents-In-Suit relate to dexmedetomidine, a chemical compound with certain sedative properties. As explained in the '214 Patent, dexmedetomidine is one form of medetomidine. Medetomidine is known as a racemic mixture, meaning that it is comprised of a molecule that exists in two forms, known as enantiomers. Each enantiomer has the same chemical formula, but the atoms of the molecule are arranged differently. (D.E. 1, Ex. A at 1:5-

[1] Citations to "Mooney Ex. __" are to the exhibits attached to the Declaration of Kyle Mooney, dated January 18, 2011 and filed herewith. Citations to "Proposed Amended Counterclaims at ¶ __" are to Sandoz Inc.'s proposed First Amended Answer, Affirmative Defenses and Counterclaims to Plaintiffs' First Amended Complaint. The amendments to Sandoz Canada's counterclaims mirror the amendments to Sandoz Inc.'s pleading.

63.) The enantiomers are mirror images of each other, and are known as the "*d*-enantiomer" and the "*l*-enantiomer."



(D.E. 1, Ex. A at Fig. 2.) For medetomidine, these enantiomers are called "*d*-medetomidine" or "dexmedetomidine," for one form, and "*l*-medetomidine" or "levomedetomidine" for the other form. (D.E. 1, Ex. A at 1:5-63.)

B. Sandoz's Initial Inequitable Conduct Allegations

On October 16, 2009, Sandoz Inc. filed its Answer, Affirmative Defenses, and Counterclaims, including affirmative defenses and counterclaims alleging inequitable conduct during prosecution of both the '214 Patent and the '867 Patent. (*See* D.E. 9, Answer, Affirmative Defenses, and Counterclaims at 9-10, 12-16, 18-21.) Sandoz Inc.'s original answer alleged inequitable conduct with respect to the '214 Patent based on Plaintiffs' intentional failure to disclose that critical data submitted in support of the patentability of the claimed invention was materially erroneous. (D.E. 9, Counterclaims at ¶¶ 9-28.) As explained in those counterclaims, the originally filed claims of the '214 Patent application were directed to, *inter alia*, the enantiomers of medetomidine and methods for separating them. (D.E. 9, Counterclaims at ¶ 13.) Sandoz Inc. alleged that to overcome the patent examiner's rejection of the claims as

obvious, Applicants pointed to the *d*-enantiomer's "surprising activity . . . with respect to the α_2-α_1-selectivity ratio," and that the selectivity of the *d*-enantiomer was "more than nine times that of the racemate" medetomidine and that this was "completely unexpected and could not be predicted." (D.E. 9, Counterclaims at ¶¶ 14-15.)

Sandoz Inc.'s initial pleadings alleged that Applicants for the '214 Patent were aware, prior to the issuance of that patent, that these representations and the data in Table 2 of the specification were materially incorrect, and that Applicants' failure to apprise the PTO of the correct data reflected a deliberate intent to deceive. (D.E. 9, Counterclaims at ¶¶ 9-28.) Sandoz Inc. alleged that Applicants, including at least Dr. Raimo Virtanen, a co-inventor of the subject matter claimed in the '214 Patent, knew that the data submitted to the PTO was unreliable because subsequent work published by Dr. Virtanen prior to the filing date of the '214 Patent application yielded significantly different results and because the results in Table 2 were contrary to the scientific understanding of the α_1-adrenergic receptor. (D.E. 9, Counterclaims at ¶¶ 18-20.) On July 1, 2010, in response to Plaintiffs' Amended Complaint joining Sandoz Canada, Sandoz Canada asserted a similar counterclaim of inequitable conduct. (D.E. 72 at ¶¶ 10-29.)

C. [REDACTED].

[REDACTED].

1. [REDACTED].

[REDACTED].

2. [REDACTED].

[REDACTED].

3. [REDACTED].

[REDACTED].

4. [REDACTED].

[REDACTED].

[REDACTED]. For example, in 1990, Dr. Virtanen and Dr. Savola wrote an article published in the European Journal of Pharmacology entitled "Central α_2 -adrenoceptors are highly stereoselective for dexmedetomidine, the dextro enantiomer of medetomidine." Eur. J. Pharm., 195 (1991) 193-199 ("Virtanen/Savola 1991"). (*Id.* at ¶ 58.) This article was received in August 1990, revised in December 1990, and accepted in January 1991. (*Id.*) The Virtanen/Savola 1991 Article reported that "Medetomidine . . . is one of the most selective and potent agonists of α_2 -adrenoreceptors known," and further that "[t]he racemic medetomidine was slightly less potent than dexmedetomidine." (*Id.*) This conclusion is contrary to Table 2 of the '214 Patent and the arguments made in support of its patentability, [REDACTED] and thus confirms that Dr. Virtanen knew that the data in Table 2 of the '214 Patent was unreliable.

[REDACTED.

5. [REDACTED].

As a co-inventor named on the '214 Patent, Dr. Virtanen signed an Inventor's Declaration stating that he would disclose all information known to him to be material to patentability, and had an ongoing duty to disclose material information to the PTO throughout the entire prosecution of the '214 Patent. (*Id.* at ¶ 65.) [REDACTED].

D. The Parties' Agreement Concerning Inequitable Conduct Allegations

On April 22, 2010, prior to the deadline to add parties and/or amend pleadings, Sandoz Inc. informed Plaintiffs of its intent to amend its pleadings, enclosing a redline copy of its proposed First Amended Answer and requesting Plaintiffs' consent to the filing. (Mooney Ex. E.) Sandoz Inc.'s April 22 proposed amendments expanded and added detail to Sandoz Inc.'s already well-pleaded allegations of inequitable conduct regarding the Patents-In-Suit. (*Id.*)

[REDACTED]. With respect to the '867 Patent, Sandoz Inc. proposed to amend its inequitable conduct allegations to reflect the results of Sandoz Inc.'s investigation identifying additional prior art known to and cited by the '867 Patent Applicants in a contemporaneous article would have been material to several asserted claims. (Mooney Ex. E, Counterclaims at ¶¶ 58-66.)

The parties entered into a stipulation providing that (1) Plaintiffs consented to filing of Sandoz Inc.'s proposed amended pleading with respect to the amendments to the inequitable conduct allegations concerning the '867 Patent and (2) if Sandoz Inc. sought leave of the Court to amend its inequitable conduct allegations relating to [REDACTED] within 30 days of the deposition of Dr. Virtanen, Plaintiffs would not oppose such motion on timeliness grounds and relief under Rule 16(b)(4) would not be required. (*Id.* at 3.) On May 4, 2010, the Court "so ordered" the agreed stipulation. (Mooney Ex. F.)

Consistent with the Stipulation and Order, Sandoz now moves for leave to amend the already well-pleaded counterclaims and affirmative defenses of inequitable conduct with respect to the '214 Patent based on [REDACTED].[2] Plaintiffs have indicated that they intend to oppose Sandoz's motion for leave to amend. (Mooney Ex. H.)

ARGUMENT

I. LEAVE TO AMEND SHOULD BE FREELY GRANTED

Leave to amend pursuant to Federal Rule of Civil Procedure 15(a) should be freely granted. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *Adams v. Gould Inc.*, 739 F.2d 858, 864 (3d Cir. 1984). While amendment rests within the sound discretion of the Court, "[t]his liberal amendment philosophy limits the district court's discretion to deny leave to amend." *Adams*, 739 F.2d at 864.

[2] [REDACTED].

"[A]bsent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless 'denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.'" *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 1173, 1196 (3d Cir. 1994) (emphasis in original)). The non-moving party bears the burden of proving that actual prejudice will result from the amendment. *See Kiser v. Gen. Elec. Co.*, 831 F.2d 423, 427-28 (3d Cir. 1987).

Under this liberal standard, Sandoz's motion for leave to amend should be granted. Sandoz's proposed amendments merely amplify already-pleaded allegations, are based on Plaintiffs' own documents, and recent deposition testimony, and Plaintiffs have had full notice of the substance of these allegations for almost nine months.

II. PLAINTIFFS CANNOT ESTABLISH THAT SANDOZ'S PROPOSED AMENDMENT WILL CAUSE UNDUE OR SUBSTANTIAL PREJUDICE

Plaintiffs cannot establish that they will be unduly or substantially prejudiced by the proposed amendments. As an initial matter, Sandoz Inc.'s and Sandoz Canada's Amended Counterclaims come within 30 days of Dr. Virtanen's deposition and thus fall within the timeframe within which Plaintiffs have stipulated that they will not object that the amendments are untimely. Plaintiffs, moreover, controlled the date of Dr. Virtanen's deposition, and, therefore, effectively set the schedule on which Sandoz Inc. and Sandoz Canada could amend their pleadings. Having done so, Plaintiffs cannot complain that the amendment would prejudice their ability to effectively respond to Sandoz's allegations.

Further, Sandoz Inc. and Sandoz Canada already have pleaded inequitable conduct based on the very same theories set forth in its proposed Amended Answer, Affirmative Defenses, and Counterclaims. For example, in Sandoz Inc.'s and Sandoz Canada's original Answer,

Affirmative Defenses, and Counterclaims, they alleged that Applicants for the '214 Patent, including at least Dr. Virtanen, must have known that the data in the patent was unreliable and did not support representations made to the PTO to overcome rejections. (D.E. 9, Counterclaims at ¶¶ 9-28.) [REDACTED].

In addition, Sandoz Inc.'s and Sandoz Canada's current pleadings are substantially similar to the proposed amended pleadings sent to Plaintiffs almost nine months ago. [REDACTED]. That Sandoz seeks only to plead additional detailed facts supporting already-pleaded inequitable conduct defenses and counterclaims belies any claim that Plaintiffs would be unduly prejudiced by the amendment. *See, e.g.*, *Webxchange Inc. v. Dell Inc.*, No. 08-132-JJF, 2010 U.S. Dist. LEXIS 4526, *6, *11-12 (D. Del. Jan. 20, 2010) (granting motion to amend inequitable conduct allegations after Rule 16(b) deadline because plaintiff not unduly prejudiced where amended allegations related to already-pleaded inequitable conduct theories).

[REDACTED]. For this separate and independent reason, any claim that Plaintiffs would be unduly prejudiced by the amendment is unavailing. *See, e.g.*, *Freres v. SPI Pharma, Inc.*, C.A. No. 06-540-GMS, 2009 U.S. Dist. LEXIS 43740, *18 (D. Del. May 21, 2009) (finding no undue prejudice and granting leave to add inequitable conduct defense and counterclaim after Rule 16(b) deadline because "[i]nformation regarding the inventors' knowledge and what they did or did not do regarding the patent specification and their representations to the PTO would primarily be within [plaintiff's] control").

Here, where Sandoz Inc. and Sandoz Canada gave Plaintiffs ample notice of their intent to plead inequitable conduct regarding [REDACTED] months ago, Plaintiffs expressly agreed that a motion to seek leave concerning amendments on this topic could be made after [REDACTED].

III. SANDOZ'S WELL-PLEADED ALLEGATIONS OF INEQUITABLE CONDUCT WOULD, IF PROVED, RENDER '214 THE PATENT UNENFORCEABLE

Sandoz Inc. and Sandoz Canada have already alleged a prima facie case of inequitable conduct based on the same theory, and which allegations are now supplemented by the proposed amendments. If proven, these allegations would render the '214 Patent unenforceable. As such, the amendments are plainly not futile.

To plead inequitable conduct, Sandoz's well-pleaded allegations must show that the applicant for a patent "(1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information; and (2) . . . did so with a specific intent to deceive the PTO." *See Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009).

Sandoz clearly has alleged that the first element of inequitable conduct and provided ample supporting detail. [REDACTED]. Sandoz alleges that by withholding this information, Dr. Virtanen failed to disclose material information to the PTO. [REDACTED].

Sandoz also has sufficiently alleged the second element, deceptive intent. Knowledge and intent may be averred generally, so long as the pleadings allege sufficient underlying facts to reasonably infer that a party acted with the requisite state of mind. *See Exergen Corp.,* 575 F.3d at 1327 n.3; *see also Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) ("Intent need not, and rarely can, be proven by direct evidence. It is most often proven by a showing of acts the natural consequences of which are presumably intended by the actor." (quotation marks omitted)). At the pleading stage, the inference of deceptive intent must merely be "reasonable and drawn from a pleading's allegations of underlying fact to satisfy Rule 9(b)." *Exergen*, 575 F.3d at 1329 n.5; s*ee also, e.g.*, *Aerocrine AB v. Apieron, Inc.*, No. 08-787, 2010 U.S. Dist. LEXIS 31176, *33-34 (D. Del. Mar. 30, 2010) (granting motion to add inequitable

conduct allegations when it could be "reasonably inferred" that applicant was aware of prior art withheld from the PTO). The following factors are relevant in finding an intent to deceive: (1) the undisclosed information was "highly material to the prosecution of the . . . patent"; (2) "the applicants knew of the [information] and knew or should have know of its materiality"; and (3) "the patentee has failed to come forward with any credible good faith explanation for the applicants' failure to disclose [the information] to the PTO." *Praxair,* 543 F.3d at 1315; *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, No. 00-1167, 2010 U.S. Dist. LEXIS 32291, at *16-20 (D.N.J. March 30, 2010) (unpublished) (denying plaintiff's motion summary judgment because the court was required to draw the *Praxair* inference in favor of defendant's argument that plaintiff's committed inequitable conduct).

Sandoz's amended pleading alleges exactly these facts. [REDACTED].

Nor are these allegations the sole support for a finding of deceptive intent. [REDACTED].

The proposed amended pleadings also exceed the particularity standard required to allege inequitable conduct under *Exergen* and Federal Rule of Civil Procedure 9(b). *See Exergen Corp.,* 575 F.3d at 1326-27 (holding that "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO"). As reflected in the chart below, Sandoz Inc.'s and Sandoz Canada's amended pleading meets *Exergen's* requirements:

***Exergen* requirement**	**Location of Information in Proposed Amended Pleading[3]**
Who: identity of the person who allegedly committed the	Dr. Virtanen (passim)

[3] Citations in this chart are to the paragraphs pleading Sandoz's Counterclaims in Sandoz's Amended Answer, Affirmative Defenses, and Counterclaims. The citations are intended to be exemplary and are not necessarily an exhaustive list of where such information can be found in Sandoz's pleadings.

inequitable conduct	
What: portions of patent allegedly implicated	Sandoz alleges that the inequitable conduct was committed as a successful attempt to convince the examiner of the unexpected results of the *d*-enantiomer of medetomidine. Because "*d*-enantiomer occurs in every claim of the '214 Patent, every claim of the patent is tainted by Virtanen's inequitable conduct. (¶ 79)
Where: location of relevant information in undisclosed material	[REDACTED].
When: time the individual become aware of allegedly undisclosed material information	[REDACTED].
How: how would the PTO have used the information	[REDACTED].

CONCLUSION

For all of the foregoing reasons, Sandoz Inc. and Sandoz Canada respectfully request that that the Court grant their motion for leave to file a proposed Amended Answers, Affirmative Defenses and Counterclaims, and grant whatever other and further relief it deems just and appropriate.

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